

§ 882.1525 Tuning fork.

(a) *Identification.* A tuning fork is a mechanical device which resonates at a given frequency and is used to diagnose hearing disorders and to test for vibratory sense.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[44 FR 51730–51778, Sept. 4, 1979, as amended at 54 FR 25051, June 12, 1989]

§ 882.1540 Galvanic skin response measurement device.

(a) *Identification.* A galvanic skin response measurement device is a device used to determine autonomic responses as psychological indicators by measuring the electrical resistance of the skin and the tissue path between two electrodes applied to the skin.

(b) *Classification.* Class II (performance standards).

§ 882.1550 Nerve conduction velocity measurement device.

(a) *Identification.* A nerve conduction velocity measurement device is a device which measures nerve conduction time by applying a stimulus, usually to a patient's peripheral nerve. This device includes the stimulator and the electronic processing equipment for measuring and displaying the nerve conduction time.

(b) *Classification.* Class II (performance standards).

§ 882.1560 Skin potential measurement device.

(a) *Identification.* A skin potential measurement device is a general diagnostic device used to measure skin voltage by means of surface skin electrodes.

(b) *Classification.* Class II (performance standards).

§ 882.1570 Powered direct-contact temperature measurement device.

(a) *Identification.* A powered direct-contact temperature measurement device is a device which contains a power source and is used to measure differences in temperature between two points on the body.

(b) *Classification.* Class II (performance standards).

§ 882.1610 Alpha monitor.

(a) *Identification.* An alpha monitor is a device with electrodes that are placed on a patient's scalp to monitor that portion of the electroencephalogram which is referred to as the alpha wave.

(b) *Classification.* Class II (performance standards).

§ 882.1620 Intracranial pressure monitoring device.

(a) *Identification.* An intracranial pressure monitoring device is a device used for short-term monitoring and recording of intracranial pressures and pressure trends. The device includes the transducer, monitor, and interconnecting hardware.

(b) *Classification.* Class II (performance standards).

§ 882.1700 Percussor.

(a) *Identification.* A percussor is a small hammerlike device used by a physician to provide light blows to a body part. A percussor is used as a diagnostic aid during physical examinations.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

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